AMENDMENTS TO THE CLAIMS

Please cancel claims 1-34 without prejudice.

Please add new claims 35 – 46.

A complete list of claims as currently amended follows:

1-34 (canceled).

35. (new) A once a day oral pharmaceutical dosage form consisting essentially of:

(a) a controlled release metformin core consisting essentially of: (i) a mixture of metformin or a pharmaceutically acceptable salt thereof and at least one pharmaceutically acceptable excipient; (ii) optionally a secondary seal coat surrounding the metformin mixture and (iii) a semipermeable membrane surrounding the metformin mixture or the secondary seal coat if present;

(b) a primary seal coat that does not contain an active pharmaceutical ingredient, that rapidly disperses or dissolves in water and that is applied to the semipermeable membrane of the controlled release metformin core; and

(c) an immediate release pioglitazone coating applied to the primary seal coat comprising:

(i) pioglitazone or a pharmaceutically acceptable salt thereof; and

(ii) a binder;

wherein the dosage form exhibits the following metformin dissolution profile when tested in a USP Type 2 apparatus at 75 rpms in 900 ml of simulated intestinal fluid and 37°C: 10-45% of the metformin is released after four hours; 30-90% of metformin is released after eight hours and wherein the dosage form exhibits the following pioglitazone dissolution profile when tested in a USP apparatus Type 1 apparatus at 100 rpm in a pH 2.0 HCl-0.3M KCl buffer solution: at least 79% of the pioglitazone is released after 20 minutes and at least 95% of the pioglitazone is release from the dosage form after 30 minutes.

36. (new) The dosage form of claim 35 wherein said controlled release metformin core is an osmotic tablet.

37. (new) The dosage form of claim 36 wherein the osmotic tablet consists essentially of:

(i) a mixture of:

(A) 50-98% of said metformin or a pharmaceutically acceptable salt thereof;

(B) 0.1-40% of a binding agent;

(C) 0-20% of an absorption enhancer; and

(D) 0-5% of a lubricant;

(ii) optionally a secondary seal coat surrounding the mixture; and

(iii) a semipermeable membrane consisting essentially of:

(A) 50-99% of a polymer;

(B) 0-40% of a flux enhancer; and

(C) 0-25% of a plasticizer,

said membrane having at least one passageway formed therein for release of the metformin or a pharmaceutically acceptable salt thereof.

38. (new) The dosage form of claim 35 wherein said metformin or pharmaceutically acceptable salt thereof is metformin hydrochloride and the pioglitazone or pharmaceutically acceptable salt thereof is pioglitazone hydrochloride.

39. (new). The dosage form of claim 35 wherein the release of the metformin or a pharmaceutically acceptable salt thereof is not regulated by an expanding polymer.

40. (new) The dosage form of claim 35 wherein said controlled release of said metformin or a pharmaceutically acceptable salt thereof provides a T_{max} of 8-12 hours.

41. (new) The dosage form of claim 35 wherein said release of the pioglitazone provides a T_{max} of 1-12 hours.

42. (new) The dosage form of claim 41 wherein said release of the pioglitazone provides a T_{max} of 1-4 hours.

43. (new) The dosage form of claim 35 wherein the immediate release pioglitazone coating comprises:

(i) pioglitazone or a pharmaceutically acceptable salt;

(ii) a binder;

(iii) a surfactant; and

(iv) a pore former.

44. (new) The dosage form of claim 35 wherein the pioglitazone coating is applied to the primary seal coating using a solvent mixture of water and an organic solvent.

45. (new) A once a day oral pharmaceutical dosage form consisting essentially of:

(a) an osmotic tablet core wherein the osmotic tablet core consists essentially of:

(i) a core consisting essentially of:

(I) 50-98% of metformin or a pharmaceutically acceptable salt thereof;

(II) 0.1-40% of a binding agent; and

(III) 0-20% of an absorption enhancer;

(ii) optionally a secondary seal coat surrounding the core; and

(iii) a semipermeable membrane consisting essentially of:

(I) 50-99% of a polymer;

(II) 0-40% of a flux enhancer and

(III) 0-25% of a plasticizer,

said membrane having at least one passageway formed therein for release of the metformin;

(b) a primary seal coat that does not contain an active pharmaceutical ingredient, that rapidly disperses or dissolves in water and that is applied to

the osmotic tablet core

(c) an immediate release pioglitazone coating consisting essentially of:

(i) pioglitazone or a pharmaceutically acceptable salt thereof; and

(ii) a binder

wherein the immediate release pioglitazone coating is applied to the primary seal coat that is applied to the osmotic tablet core using a solvent mixture comprising water and an organic solvent and wherein the dosage form provides a T_{max} of 8-12 hours for the metformin and a T_{max} of 1-4 hours for the pioglitazone and wherein the dosage form exhibits the following dissolution profile when tested in a USP Type 2 apparatus at 75 rpms in 900 ml of simulated intestinal fluid and 37°C: 10-45% of the metformin is released after four hours; 30-90% of metformin is released after eight hours and wherein the dosage form exhibits the following pioglitazone dissolution profile when tested in a USP apparatus Type 1 apparatus at 100 rpm in a pH 2.0 HCl-0.3M KCl buffer solution: at least 79% of the pioglitazone is released after 20 minutes and at least 95% of the pioglitazone is release from the dosage form after 30 minutes.

46. (new) The dosage form of claim 45 wherein the immediate release pioglitazone coating further comprises:

(i) pioglitazone or a pharmaceutically acceptable salt;

(ii) a binder;

(iii) a surfactant; and

(iv) a pore former.